William J. O'Shaughnessy
Ravin R. Patel
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 639-2094
woshaughnessy@mccarter.com

Attorneys for Novartis Pharmaceuticals Corporation

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Lisa J. Pirozzolo
Kevin S. Prussia
Sean K. Thompson
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Tracey C. Allen
Amanda L. Major
Rachel L. Weiner
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, N.W.
Washington, DC 20006
(202) 663-6000

Attorneys for Novartis Pharmaceuticals Corporation

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. SAGENT PHARMACEUTICALS, INC. Defendant.	Civil Action No. _____

COMPLAINT

1. Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") alleges as follows on personal knowledge as to its own actions and observations and on information and belief as to all other facts.

NATURE OF THE ACTION

2. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of Defendant's application for approval from the U.S. Food and Drug Administration ("FDA") to manufacture, market, and sell 4 mg / 5 mL vials of zoledronic acid concentrate, which is a generic version of the 4 mg / 5 mL concentrate form of Novartis's Zometa® product, prior to the expiration of U.S. Patent No. 8,324,189 ("the '189 patent").

RELATED ACTIONS

3. Novartis has filed several other patent infringement actions currently pending before the Court involving infringement of the '189 patent, including *Novartis Pharmaceuticals Corporation et al. v. Wockhardt USA LLC et al.*, Civil Action No. 2:12-cv-03967-SDW-MCA (Consolidated).

THE PARTIES

A. Novartis

4. Plaintiff Novartis is a corporation organized under Delaware law. Its principal place of business is in East Hanover, New Jersey.

B. Sagent Pharmaceuticals, Inc.

5. Sagent Pharmaceuticals, Inc. ("Sagent") is a corporation organized under Delaware law. Its principal place of business is in Schaumburg, Illinois. Upon information and belief, Sagent has systematic and continuous contacts with New Jersey, including engagements to strategically develop, market, deliver, and/or sell generic products in New Jersey.

6. Upon information and belief, Sagent submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 091493, seeking approval to market a generic version of Zometa®. Upon information and belief, Sagent is selling and/or distributing three other zoledronic acid products, including generic versions of Novartis's Zometa® Reclast® in New Jersey.

7. Sagent has availed itself of the legal protections of the State of New Jersey by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

9. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

10. This Court has personal jurisdiction over Sagent for the following reasons, among others:

a) Sagent has systematic and continuous contacts with New Jersey, in that, among other things, it sells, imports, and/or distributes generic drugs in New Jersey and, thus, has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being hauled into court in this district;

b) Sagent is seeking approval to sell and/or distribute a generic version of Zometa® in New Jersey;

c) Sagent sent notification of its Paragraph IV certification to Novartis in New Jersey;

d) Novartis, which will be harmed by the Sagent's actions, is domiciled in New Jersey; and

e) Sagent has previously acquiesced to personal jurisdiction and asserted counterclaims in this jurisdiction, including in related matter *Novartis Pharmaceuticals Corporation et al. v. Wockhardt USA LLC et al.*, Civil Action No. 2:12-cv-03967-SDW-MCA (consolidated).

STATEMENT OF FACTS

A. Novartis's Zometa Product

11. Novartis is the holder of New Drug Applications ("NDA") No. 21-223 by which the FDA granted approval for the marketing and sale of Zometa®. The active ingredient in Zometa® is zoledronic acid. Zometa® was first approved by the FDA in 2001 and is approved to treat hypercalcemia of malignancy (HCM), a condition resulting in high calcium blood levels due

to cancer, multiple myeloma, and bone metastases from solid tumors. Zometa®'s primary indication is for the prevention of skeletal-related complications associated with cancer, such as fractures and pain.

12. Zometa® is administered intravenously and presently sold in two dosage forms and strengths: (i) a 4 mg / 100 mL ready to use bottle and (ii) a 4 mg / 5 mL vial of concentrate.

B. The Patent-In-Suit

13. The '189 patent, entitled "Use of zolendronate for the manufacture of a medicament for the treatment of bone metabolism diseases," was duly and legally issued on December 4, 2012. Novartis is the owner of the '189 patent, with the right to sue for and obtain equitable relief and damages for infringement of the '189 patent. A copy of the '189 patent is attached as Exhibit A. The claims of the '189 patent are valid and enforceable.

14. The approved method of administration for Zometa® is covered by certain claims of the '189 patent. Accordingly, the '189 patent is listed in connection with Zometa® in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is also referred to as the "Orange Book." Accordingly, Sagent has actual or constructive knowledge of the patent.

C. Sagent's Proposed Generic Zometa® Product

15. By letter dated October 22, 2013, Sagent notified Novartis that it had submitted to the FDA ANDA No. 091493 pursuant to 21 U.S.C. § 355(j)(2)(B), seeking approval to engage in the commercial manufacture, use, and sale of 4 mg / 5 mL vials of zoledronic acid concentrate ("Sagent's Proposed Generic Zometa® Product") before expiration of the '189 patent.

16. By filing ANDA No. 091493, Sagent has necessarily represented to the FDA that Sagent's Proposed Generic Zometa® Product has the same active ingredient, route of administration, dosage form, and strength as 4 mg / 5 mL vial of Zometa®.

17. In the notice letter, Sagent stated that its application included a Paragraph IV Certification with respect to the '189 patent, alleging that the '189 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Sagent's Proposed Generic Zometa® Product.

18. This action is being commenced before expiration of forty-five days from Novartis's receipt of Sagent's notice letter.

COUNT I (INFRINGEMENT OF THE '189 PATENT)

19. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth herein.

20. Upon information and belief, Sagent knew of the '189 patent when it submitted ANDA No. 091493, and knows or is willfully blind to the fact that its actions will induce or contribute to direct infringement of the '189 patent.

21. Sagent's submission of ANDA No. 091493, for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Sagent's Proposed Generic Zometa® Product before the expiration of the '189 patent constitutes an act of infringement of one or more claims of the '189 patent under 35 U.S.C. § 271(e)(2).

22. Sagent had actual and constructive knowledge of the '189 patent prior to filing ANDA No. 091493 and was aware that filing ANDA No. 091493 with the FDA constituted an act of infringement of one or more claims of the '189 patent.

23. Upon FDA approval of Sagent's ANDA No. 091493, Sagent will further infringe the '189 patent by making, using, offering to sell, and selling Sagent's Proposed Generic Zometa®

Product in the United States and/or importing such product into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(b)-(c) unless enjoined by the Court.

24. If Sagent's infringement of the '189 patent is not enjoined, Novartis will suffer irreparable injury for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis requests entry of judgment in its favor and against Sagent as follows:

1. A judgment that one or more claims of the '189 patent are infringed by Sagent's submission of ANDA No. 091493, and that Sagent's making, using, offering to sell, or selling in the United States, or importing into the United States, the Sagent Proposed Generic Zometa® Product will infringe, directly or indirectly, one or more claims of the '189 patent;

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 091493 shall be the date which is not earlier than the expiration date of the '189 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

3. An order permanently enjoining Sagent, and its affiliates, subsidiaries, officers, agents, servants, and employees and those acting in privity or in concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States, the Sagent Proposed Generic Zometa® Product until after the expiration date of the '189 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

4. Damages or other monetary relief to Novartis if Sagent engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Sagent Proposed Generic Zometa® Product prior to the expiration date of the '189 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: December 3, 2014

s/William J. O'Shaughnessy
William J. O'Shaughnessy
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 639-2094
woshaughnessy@mccarter.com

Attorneys for Novartis Pharmaceuticals Corporation

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I certify that to the best of my knowledge, the matter in controversy is the subject of the following actions:

- *Novartis Pharmaceuticals Corporation et al. v. Wockhardt USA LLC et al.*, Civil Action No. 2:12-cv-03967-SDW-MCA (consolidated) filed on June 27, 2012 in the District of New Jersey;
- *Novartis Pharmaceuticals Corporation et al. v. Fresenius Kabi USA, LLC*, Civil Action No. 2:13-cv-07914-SDW-MCA filed on December 27, 2013 in the District of New Jersey; and
- *Novartis Pharmaceuticals Corporation et al. v. Pharmaceutics International, Inc.*, Civil Action No. 2:14-cv-01347-SDW-MCA filed on March 3, 2014 in the District of New Jersey.

Dated: December 3, 2014

Respectfully Submitted,

s/William J. O'Shaughnessy
William J. O'Shaughnessy
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
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